DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Ascension Orthopedics, Incorporated
Ms. Susan Walton
Director, Regulatory Affairs
8700 Cameron Road, Suite 100
Austin, Texas 78754

Re: K130050
Trade/Device Name: Integra TITAN Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: May 14, 2013
Received: May 17, 2013

Dear Ms. Walton:

This letter corrects our substantially equivalent letter of June 18, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use Statement

510(K) Number: K130050

Device Name: Integra TITAN Reverse Shoulder System

Indications for Use:

The Titan™ Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The glenoid base plate is intended for cementless application with the addition of screws for fixation.

The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

JUN 1 8 2013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS			
SPONSOR	Ascension Orthopedics, Inc. A wholly owned division of Integra LifeSciences, Inc. 8700 Cameron Road Austin, TX 78754-3832		
510(k) CONTACT:	Susan Walton susan.walton@integralife.com Phone: (512) 836-5001 x1591 FAX (512) 836-6933		
DATE PREPARED:	January 5, 2013		
TRADE NAME:	Integra TITAN Reverse Shoulder System		
COMMON NAME:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented		
CLASSIFICATION:	21 CFR 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis		
PRODUCT CODE:	KWS		
PANEL:	Orthopedic		
PREDICATE DEVICES:	K081016	Promos Reverse Shoulder System	Smith & Nephew Inc.
	K113523 K110598	SMR Reverse Shoulder System	Lima Corporate S.P.A.
	K120174 K062250	Delta Xtend Reverse Shoulder System	DePuy, Inc.
	K041066	Encore Reverse Shoulder Prosthesis	DJO Surgical/Encore Medical
	K120739	Aequalis Adjustable Reverse Shoulder System	Tornier Inc.

DEVICE DESCRIPTION:	The Integra TITAN Reverse Shoulder System is a semi-constrained modular total shoulder construct. The humeral components consist of humeral stems, varying heights of reverse bodies, and humeral poly liners. The poly liners are available in varying thicknesses and constraints to achieve stability and offset of the glenohumeral joint. The variable length reverse bodies and proximally-filling shape are designed to accommodate the natural humeral geometry, providing stable fixation as well as proximal bone loading. The glenoid components are composed of a baseplate secured by a central compression screw and 4 peripheral screws, two of which can be locked. A glenosphere is attached to the baseplate via taper lock. Glenospheres are available in varying offsets and lateralizations.
INTENDED USE:	The Titan™ Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The glenoid base plate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	Feature/ Characteristic	*TITAN Reverse Shoulder System* (Subject Device)
	Implant Design	• Modular design comprised of humeral stem, reverse body, polyethylene insert, glenoid base, eccentric and concentric glenosphere, glenoids baseplate and bone screw.
	Components – Humeral Stem	
	Materials	• Cobalt Chromium alloy – cemented • Titanium alloy – press fit
	Sizes	90mm Length Press Fit Stem • 11 diameters (6-16mm) 90mm Length Cemented Stem • 5 diameters (6-14mm) Revision Stems • Two lengths – 125 and 165mm • 4 diameters (8-14mm)
	Components – Reverse Body	
	Materials	• Titanium alloy with porous coating
	Sizes	142.5° inclination angle available in 3 body heights
	Components – Insert	
	Materials	• UHMWPE
	Sizes	• Standard – 4 sizes • Retentive – 4 sizes
	Components – Baseplate and Screws	
	Materials	• Titanium alloy with asymmetrical titanium bead sintered coating
	Sizes	• Two lengths • Convex back • Titanium central compression screw • Titanium peripheral polyaxial locking and non-locking screws
	Components – Glenosphere	
	Materials	• Cobalt chromium alloy
	Sizes	• Concentric design in 2 sizes, lateralized • Eccentric design in 3 sizes, lateralized
	Sterilization	• Provided sterile • Gamma radiation
NONCLINICAL TESTING	The Integra TITAN Reverse Shoulder System has undergone performance testing to confirm the system's ability to perform under expected clinical conditions. 1. <u>TP/TR -04-0172 rev A TSS Taper Axial Disassembly Force</u> This test report was previously submitted in K100448. The taper in the TITAN Total Shoulder System is identical to the taper in the Reverse Shoulder system therefore additional testing was not required. The test report concludes that the locking efficiency of the AOI taper is acceptable. 2. <u>TP/TR-04-0245 Rev B TITAN Reverse Shoulder Body/Spacer to Liner Axial Disassembly Test</u> The objective of this test was to verify that the force required to disassemble the TITAN Reverse Shoulder System (RSS) humeral liner from the modular body or the humeral spacer exceeds a biomechanically justified worst case load. The Spacer and Liner assemblies of the TITAN Reverse Shoulder System met all acceptance criteria.	

3. TP/TR-04-0248 Dynamic Evaluation of Glenoid Baseplate Disassociation
The objective of this test was to verify that the TITAN Reverse Shoulder System (RSS) glenoid assembly does not loosen during cyclic loading representing one year of post-arthroplasty daily living. The TITAN Reverse Shoulder System Glenoid construct met all acceptance criteria.

4. TP/TR -04-0283 rev A RSS Fatigue Evaluation Test
The objective of this test was to verify that the modular TITAN Reverse Shoulder System (RSS) maintains functional integrity after enduring a challenging fatigue regimen representing 10 years of daily worst case post-arthroplasty cyclic loading in a simulated biological corrosive environment. The TITAN Reverse Shoulder System met all acceptance criteria.

5. TP/TR-04-0254-01 TITAN Reverse Shoulder System Glenosphere-Baseplate Taper Axial Disassembly Force
The purpose of this test was to determine the force required to disassemble the Glenosphere/Baseplate taper junction of the Integra TITAN Reverse Shoulder System. Heuristic models of the Reverse glenosphere male taper and baseplate female taper were tested as per ASTM F2009-00(2011). The taper design for the Glenosphere-Baseplate junction of the TITAN Reverse Shoulder System met all acceptance criteria.

6. TP/TR-04-0281 Rev A Reverse Shoulder System Liner Rotational Resistance Test Protocol
The objective of this test was to verify that the TITAN Reverse Shoulder System (RSS) humeral liner could withstand worst case torques created by rotation about the glenosphere without disassociating from the body implant or spacer implant. The rotational resistance at the interface of the Spacer and Liner of the TITAN Reverse Shoulder System met all acceptance criteria.

7. TP/TR-09-0082 Reverse Shoulder 4.5mm Screw Properties
The purpose of this test was to verify that the TITAN Reverse Shoulder System (RSS) 4.5mm screw meets all criteria for its intended use. These criteria include driving properties, torsional properties and axial pullout strength. The RSS 4.5mm screws met all acceptance criteria.

8. TP/TR-09-0083 Reverse Shoulder 5.5mm Screw Properties
The purpose of this test was to verify that the TITAN Reverse Shoulder System (RSS) 5.5mm screw meets all criteria for its intended use. These criteria include driving properties, torsional properties and axial pullout strength. The RSS 5.5mm screws met all acceptance criteria.

9. TR-09-0088 rev C Asymmatrix Coating Characteristics
The Humeral Bodies and Glenoid Baseplates of the Integra TITAN Reverse Shoulder System will be coated with Asymmatrix coating, a sintered asymmetrical titanium bead coating manufactured by Orchid Orthopedic Solutions, Memphis, Tennessee. The purpose of this document is to demonstrate that this coating meets the requirements for its intended use as provided in two FDA guidance documents. The Asymmatrix coating meets the requirements of the appropriate FDA guidance documents for use in the Integra Reverse Shoulder System.

10. TR-09-0249 rev B RSS Range of Motion
This document verifies the range of motion of the TITAN Reverse Shoulder System in flexion, abduction, internal rotation, external rotation and extension. The range of motion of the TITAN Reverse Shoulder System meets the performance requirements.

The testing was conducted on worst case components or constructs according to standard test

	methods, where possible.
CLINICAL PERFORMANCE DATA:	Clinical performance data were not necessary to support substantial equivalence.
BASIS OF SUBSTANTIAL EQUIVALENCE:	The TITAN Reverse Shoulder system is similar to the predicate devices in terms of indications for use, intended use and fundamental scientific technology. Performance data demonstrates that the subject device design is expected to perform as indicated.